

Evaluation of the complications in laparoscopic retroperitoneal radical nephrectomy; An experience of high volume centre

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Summary *Objectives: To provide a standardised report of complications after retroperitoneal laparoscopic radical nephrectomy (rLRN) in a high-volume centre using Clavien-Dindo classification.*

Materials and methods: We analysed records maintained in a prospective database of 330 consecutive patients that underwent rLRN between March 1995 and September 2016. All complications were graded according to the modified Clavien-Dindo classification. Three generations of surgeons were defined and the learning curve in rLRN was evaluated by comparing the first 100 cases (Group A) performed by first-generation surgeons with the last 100 cases (Group B) by third-generation surgeons.

Results: The mean age of our cohort was 66 ± 11.9 years. The overall complication rate was 19.7%. The majority of complications (12.7%) were Clavien 1 (5.1%) and Clavien 2 (7.6%) and did not require any interventions; blood transfusion was the most frequently encountered intervention (4.8%). Half of which were because of major intraoperative bleeding. Mortality rate was 0.9%. We found a trend towards lower complication rate in group B (19%) compared to group A (23%); this was mainly because of the reduction in the incidence of Clavien 1 and 2 complications. The pathological stage varied significantly in the two groups while the rate of negative surgical margins was comparable.

Conclusions: rLRN is a safe procedure with an acceptable rate of complications. The learning curve was shorter for the third-generation surgeons (group B); although these surgeons operated on a significantly higher number of patients with more advanced diseases. The Clavien-Dindo classification is suitable for assessing rLRN complications. Adopting this standardised system can help in the evaluation and comparison of surgical quality of LRN series.

KEY WORDS: Laparoscopy; Kidney cancer; Complications; Clavien-Dindo classification.

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INTRODUCTION

Renal cell carcinoma (RCC) is the most common malignant tumour of the kidney parenchyma, representing approximately 2% of all new cases of cancer and accounting for over 80% of all neoplasms that affect the

kidney (1). Radical nephrectomy (RN) remains the gold standard surgical treatment for patients with RCC when nephron-sparing procedures are not feasible (2). Over the past two decades, with advancements in laparoscopic surgery, laparoscopic RN (LRN) has become a widely available surgical option that has been shown to provide similar oncological outcomes to open surgical techniques with the well-known benefits of laparoscopic approach (3-5). At present, it is regarded as a standard treatment worldwide with up to 80% of urologists offering LRN to patients with localised RC (6). LRN can be performed by two different approaches, namely the retroperitoneal route or the transperitoneal route.

The retroperitoneal approach, which was developed to mimic open-flank nephrectomy, allows rapid and direct access to the renal pedicle without violating the peritoneal cavity. Thus, retroperitoneal LRN (rLRN) can minimise the risk of some complications, such as visceral organ injuries. The European Guidelines on Reporting and Grading of Complications After Urologic Surgical Procedures were recently published (7). The key recommendations of these guidelines include the use of a standardised system, such as the Clavien-Dindo grading system (8), and the provision of a table of all complications and corresponding scores or a list of the complications by scores. Complication rates are still one of the most frequently used surrogate indicators for the quality of surgery. However, to the best of our knowledge, no data have been published on rLRN complications using standardised classifications. In this study, we report on our large, single-institution rLRN series, representing over 15 years of experience. The purpose of the study is to determine the complication rates after rLRN using a standardised method, namely the Clavien-Dindo classification, in a large cohort at a pioneering institution.

MATERIALS AND METHODS

Between March 1995 and September 2016, 380 consecutive LRN surgeries were performed for patients with renal tumours (stage T1-T4) at our institution. All patients were counselled appropriately about the treat-

No conflict of interest declared.

ment and the aim of this study with written informed consent obtained prior to the surgery. In our centre, the preferred laparoscopic approach is the retroperitoneal route which was first described by Gaur (9) and later modified and developed by Rassweiler *et al.* (10, 11).

All data were recorded prospectively using a Microsoft Office Excel spreadsheet. We excluded cases that were performed via transperitoneal laparoscopic approach or open surgery, those with less than 12 months of follow-up or missing follow-up data and patients with additional cancer or bilateral renal tumours. Thus, 330 patients with complete follow up were enrolled in the study.

The review board of our certified cancer centre approved our prospective collection of patients' data.

In the first 50 cases, the specimen was entrapped in an organ retrieval bag and extracted via a flank incision without prior morcellation. Afterwards, we preferred to extract the specimen through a Gibson incision.

All patients stayed in the *intensive care unit* (ICU) for the first 24 hours after the operation and received antibiotics for a minimum of 3 days in the postoperative period.

Three generations of surgeons were defined as follows: first-generation surgeons had previous experience in open surgery but no laparoscopic training; second-generation surgeons had experience in open surgery, and they were trained by first-generation surgeons; and third-generation surgeons had no or limited experience in open surgery, and they were trained by first-or second-generation surgeons (12). The learning curves of the first- and third-generation surgeons were compared and analysed based on the results of the first 100 and last 100 cases.

Data collection

Demographic data, including age (years), gender, comorbidities, body mass index (BMI; kg/m²), operation history, tumour size (mm), tumour side and preoperative clinical stage, were recorded. Operative and postoperative data, including operation time; estimated blood loss; conversion to open surgery; length of hospital stay and duration of surgical drains; were also noted. All pathological specimens were reviewed by a single, experienced pathologist; the pathology results, including tumour staging, were evaluated according to the revised 2009 TNM classification (13). Complications were noted in detail, including treatment and outcomes, as part of our internal quality management system.

Complication assessments and follow-up schedule

All the charts, including the medical records, of patients with identified postoperative complications were reviewed and grouped according to the modified Clavien-Dindo classification (Table 1). Medical and surgical complications during the first 6 weeks were evaluated at the end of this period using our institution's medical records and reports from the rehabilitation centre and other physicians. Patients were followed up every 3 months for the first 2 years after surgery then 6 monthly thereafter.

Statistical analyses

All data were recorded in Microsoft Excel files. For statistical analysis, we used a commercially available software package (SPSS v16.0; SPSS, Chicago, IL, USA)

including the Pearson χ^2 test. A p-value < 0.05 was considered statistically significant.

RESULTS

Patient clinico-pathological characteristics and distribution of complications

This study included 330 patients who underwent rLRN performed by one of six surgeons at a single centre. The median follow-up time was 33 ± 9.8 months. Demographic, intraoperative and pathological data are presented in Table 2.

Seventy-three postoperative complications were identified in 63 patients (19.1%). In 52 patients (82.5%), only one complication was recorded, while 11 patients (17.5%) had two or more complications. As recommended by Dindo *et al.* (8), when one complication was clearly related to another, only the more severe one was labelled and reported.

Hence, we reported a complication rate of 19.7% (65 complications), as eight patients had received concomitant blood transfusion with more severe complications (four conversions and four open revisions).

Minor complications that needed no or non-interventional treatments represented 12.7% of all those reported (Clavien 1: 5.1%; Clavien 2: 7.6%; Table 1).

Complications requiring reintervention with or without anaesthesia occurred in 6% of cases (Clavien 3a: 1.5%; Clavien 3b: 2.1%; Clavien 4a: 2.1%; Clavien 4b: 0.3%). The mortality rate was 0.9% (Clavien 5).

The conversion rate was 2.1%, with half the cases requir-

Table 1.
Complication assessment according to modified Clavien-Dindo classifications.

Grade	Definition
Clavien 1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Acceptable therapeutic regimens are: drugs as anti-emetics, antipyretics, analgesics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
Clavien 2	Complications requiring pharmacological treatment with drugs other than such allowed for grade 1 complications. Blood transfusions and total parenteral nutrition are also included.
Clavien 3a	Complications needing surgical, endoscopic, or radiologic intervention under local anaesthesia.
Clavien 3b	Complications needing surgical, endoscopic, or radiologic intervention under general anaesthesia (including dialysis).
Clavien 4a	Life-threatening complications requiring ICU management: single organ dysfunction.
Clavien 4b	Life-threatening complications requiring ICU1 management: multiorgan dysfunction.
Clavien 5	Death of the patient.
Suffix 'd'	If the patient suffers from a complication at the time of discharge, the suffix "d" (for 'disability') is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

ICU1 = Intensive care unit.

Table 2.
Demographic, operative and postoperative data of patients.

Age (year)	Mean (± SD): 66 ± 11.9
Gender	Male: 207 (62.7%), Female: 123 (37.2%)
BMI¹, kg/m² (%)	≤ 25 (normal weight): 141 (42.7%) 26-30 (obesity I ^o): 133 (40.3%) 31-40 (obesity II ^o): 47 (14.2%) > 41 (obesity III ^o): 9 (2.7%) Mean BMI (± SD): 27.1 ± 5.1
Tumour side:	Left: 177 (53.6%), Right: 153 (46.3%)
Tumour size (mm):	Mean (± SD): 58 ± 15.3 Range: 30-120
Operation time (min):	Mean (± SD): 143 ± 46.3
Mean Estimated Blood Loss (ml):	155
Blood transfusion rate:	32 (9.6%)
Concomitant adrenalectomy	154 (46.6%)
Tumour histology	Clear cell RCC ² - 254 (76.9%) Papillary - 26 (7.9%) Chromophobe - 12 (3.6%) TCC ³ - 5 (1.5%) Other malignancies - 8 (2.4%) Benign - 25 (7.5%; Oncocytoma - 14 [4.2%])
Pathological T stage (pT), no. (%)	pT1 - 147 (48.2%) pT2 - 62 (20.3%) pT3 - 89 (29.2%) pT4 - 7 (2.3%)
Fuhrman grade, no. (%)	Fuhrman I - 54 (18.5%) Fuhrman II - 155 (53.1%) Fuhrman III - 73 (25%) Fuhrman IV - 10 (3.4%)
Surgical margins, no. (%)	NSM ⁴ (R0) - 298 (97.7%) PSM ⁵ (R1) - 7 (2.3%)

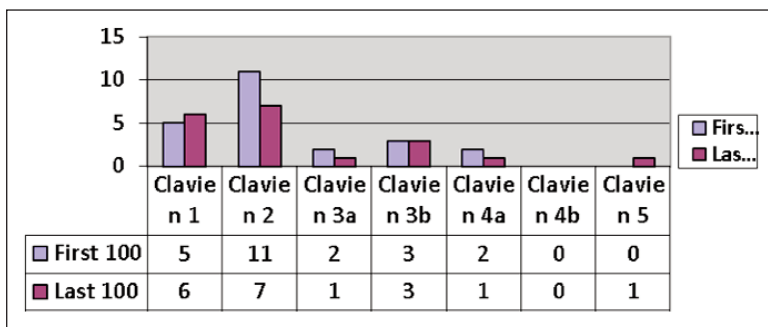
BMI¹: Body mass index; RCC²: Renal cell carcinoma; TCC³: Transitional cell carcinoma;
NSM⁴: Negative surgical margin; PSM⁵: Positive surgical margin.

ing open conversion because of uncontrollable intraoperative bleeding. The most frequent complication was anaemia requiring transfusions, which occurred in 4.8% of cases. Detailed information on each category of complications and their management is presented in Table 3.

Analysis of the learning curve

To analyse the learning curves of the first- and third-generation surgeons, we compared the first 100 cases (group A) with the last 100 cases (group B). There was no significant difference in demographic data in these groups (Table 4); the intraoperative records were also similar.

Figure 1.
Complication rates by grade in first and last 100 cases.



The operative time was comparable between the two groups (135 min vs. 128 min in group A and group B, respectively), with no significant difference in average tumour size (46 mm vs. 62 mm) or estimated blood loss (140 ml vs. 100 ml).

There was, however, a significant difference in pathological tumour stage between the two groups. In group A, 73% (68 patients) of patients that had malignant pathology were found to have pT1-tumours compared to only 30% of cases in group B. Whereas, third-generation surgeons treated significantly more patients with pT3 disease (45.6% vs. 12.9%; p < 0.001). Despite the increased complexity of cases performed by the last generation of surgeons, the rates of negative surgical margins were similar in both groups (98.9% vs. 94.6%), and the total complication rates were comparable (23% vs. 19%), (p = 0.04%). The conversion rates were similar in both groups, while blood transfusion rates were higher in the first 100 cases. This trend in reduction of overall complication rates was mainly because of the lower incidence of Clavien 1 and Clavien 2 complications (blood transfusions, infections, etc.) (Figure 1). The complication rates were higher for the first 40 cases in the first group and the first 25 cases in the second group. Complication rates and institutional learning curves are also influenced by technical and technological developments over time.

DISCUSSION

In the present study, we summarised rLRN complications according to the Clavien-Dindo classification. To the best of our knowledge, this is the first detailed report on this issue. It is well-accepted that successful operative and patients'outcomes can be supported through standardised postoperative complication classifications.

Comparison with other series

In 2004, the Clavien-Dindo classification system for reporting postoperative complications was introduced and successfully validated in general surgery (8). It has been successfully employed in case series for reporting complications in urological procedures such as transurethral prostate resection; percutaneous nephrolithotomy; laparoscopic live-donor nephrectomy; and laparoscopic, robotic-assisted and retropubic radical prostatectomy (12, 14-20). However, after more than a decade, it is still not frequently used in all fields of minimally invasive urological surgeries. Using the modified Clavien-Dindo classification, we observed a complication rate of 19.7% in a prospective series of 330 consecutive rLRN. *Abhou et al.* (5) reported similar findings: their rLRN overall complication rate was 8%. However, they may have observed lower complication rates because they used the old version of the Clavien classification system. Similarly, *Gill et al.* (21) observed a complication rate of 13% in a series of 34 rLRN surgeries for suspected kidney cancer. The complications in this study were only

Table 3.
Detailed analysis of Clavien-Dindo complications.

Complication	Management of complications	n, (%)
Clavien grade 1		
Surgical site hematoma	No special therapy (topic ointment)	6 (1.8)
Recurrent pain at surgical site	Oral analgesics	2 (0.6)
Ileus	Laxatives, parenteral alimentation	2 (0.6)
Minor bladder tamponade	Bladder irrigation through catheter	2 (0.6)
Allergic exanthema	Antibiotic discontinuation	1 (0.3)
Diarrhoea caused by antibiotics	Antibiotic discontinuation, fluid replacement, lmodium	1 (0.3)
Pneumopericardium	No special therapy	1 (0.3)
Urinary retention after catheter removal	Re-catheterization without cystoscopy	1 (0.3)
Subcutaneous emphysema	No special therapy	1 (0.3)
Total n/N, (%)		17/330 (5.1)
Clavien grade 2		
Anaemia without additional complications	Transfusion	16 (4.8)
Urinary tract infection	Parenteral antibiotics	3 (0.9)
Other site infection	Parenteral antibiotics	4 (1.2)
Persistent postoperative fever	Parenteral antibiotics	2 (0.6)
Total n/N, (%)		25/330 (7.5)
Clavien grade 3a		
Infection of the surgical site/ delayed healing	Secondary suture	3 (0.9)
Recurrent nausea and vomiting, reflux oesophagitis grade 1	Gastroscopy and PPI ¹ therapy (Esomeprazol 20 mg-7 days)	1 (0.3)
Acute gastritis, duodenal ulcer, due to an increased need for analgesics over time	Gastroduodenoscopy, PPI therapy (Pantoprazole 20 mg-5 days)	1 (0.3)
Total n/N, (%)		5/330 (1.5)
Clavien grade 3b		
Major intraoperative bleeding (vascular injury, vena cava rupture)	Conversion	4 (1.2)
Intraoperative visceral injury	Conversion	1 (0.3)
Lymph nodes; Vena Cava adhesion	Conversion	2 (0.6)
Total n/N, (%)		7/330 (2.1)
Clavien grade 4a		
Major postoperative bleeding (1 patient with intracerebral bleeding and left hemiparesis)	Open revision, transfusions, treatment in ICU ²	3 (0.9)
Cardiac decompensation, potentially lethal arrhythmias	Implantation of a permanent cardiac pacemaker, treatment in the ICU	2 (0.6)
Allergic shock caused by changes in antihypertensive medication (Enalapril)	Medical treatment in the ICU	1 (0.3)
Massive bleeding from oesophageal ulcers	Endoscopic clipping of the bleeding sites, transfusion, treatment in ICU	1 (0.3)
Total n/N, (%)		7/330 (2.1)
Clavien grade 4b		
Asystole, acute renal failure, thrombocytopenia respiratory insufficiency	Successful cardio-pulmonary resuscitation, hemodialysis, tracheostomy, artificial respiration, treatment in ICU	1 (0.3)
Total n/N, (%)		1/330 (0.3)
Clavien grade 5		
Cardiogenic shock, perioperative NSTEMI ³ , acute renal failure	Failed bradycardia resuscitation, circulatory insufficiency	1 (0.3)
Acute-on-chronic renal failure, SIRS ⁴ , left kidney infarct	Failed cardio respiratory resuscitation	1 (0.3)
Fulminant pulmonary embolism 2 nd day after the procedure	Failed cardio respiratory resuscitation	1 (0.3)
Total n/N, (%)		3/330 (0.9)

PPi¹: Proton pump inhibitors, ICU²: Intensive care Unit, NSTEMI³: Non-ST segment elevation myocardial infarction, SIRS⁴: Systemic Inflammatory Response Syndrome.

summarised as minor and major complications, without using a standardised classification system to define the complications; nevertheless, the study underlines rLRN's feasibility, reproducibility and relatively low complication rate compared to open retroperitoneal approach.

Finally, *Clavien and Dindo* (8) revised and externally validated the pre-existing classification system for postoperative complications in 2004. The new system was considered to be simple, logical, reproducible, useful and comprehensive.

Permponghosolet al. (22) used Clavien-Dindo classification to assess the complications associated with urological laparoscopic surgery. In this study, the authors observed a total complication rate of 22.1% after more than 2700 laparoscopic procedures. In the LRN group, complications occurred in 20% of the patients. Conversion to open surgery occurred in 2.9% (16 patients) of cases, while the mortality rate was 0.2%. We reported seven open conversions (2.1%) that we graded as Clavien 3b. A collaborative review by *Breda et al.* (23) concluded that although the retroperitoneal approach has the disadvantage of a smaller working space with no anatomical landmarks, it offers the clear advantage of rapid and direct access to the renal hilum. In addition, as in our experience, the incidence of adjacent organ injuries is extremely low. Most major intra operative complications encountered in the retroperitoneal approach were related to vascular injuries. In previous studies, the complication rates ranged from 8 to 22% (5, 21-23). However, the common limitation of these studies is difficulty in comparing similar surgical techniques in terms of postoperative complications due to a lack of a consensus on reporting postoperative complications in the literature. Because our study used a standardised system, it can address this limitation. Another point to consider is that all these complication rates may show a learning curve (24). Indeed, rLRN has a relatively steep learning curve; we found that a surgeon could reach a plateau after 40 cases in the first generation, where as a third-generation surgeon could reach a plateau after 25 cases. This shortening of the learning curve may have resulted from our standardized laparoscopic training

Table 4.
Demographic, operative and postoperative data of first 100 cases and last 100 cases.

Parameters	Group A (First 100)	Group B (Last 100)	p value
Age (years)	65 ± 12.6	67 ± 11.1	0.2
Gender			0.4
Male	59	66	
Female	41	34	
BMI (kg/m ²)			0.5
≤ 25 (normal weight)	46	41	
26-30 (obesity I°)	42	44	
31-40 (obesity II°)	9	10	
> 41 (obesity III°)	3	5	
Tumour size (mm)	46 ± 2.3	62 ± 3.2	0.3
Tumour side			0.4
Left	56	61	
Right	44	39	
Operation time (min)	135 ± 41.5	128 ± 43.4	0.2
EBL (ml)	140 ± 38.4	100 ± 43.7	0.5
Blood transfusion rate (n)	9	6	0.2
Tumour histology			
Clear cell RCC	84	71	0.5
Chromophobe	5	3	
Papillary	2	9	
TCC	2	6	
Benign	7	7	
Liposarcoma	-	1	
Metastasis	-	2	
Nephroblastoma	-	1	
Pathological T stage no. (%)			0.001*
pT1	68 (73.1%)	27 (30%)	
pT2	13 (14%)	16 (17.8)	
pT3	12 (12.9%)	41 (45.6%)	
pT4	0	6 (6.5%)	
Fuhrman grade, no. (%)			0.07
Grade I	32 (35.2%)	10 (12%)	
Grade II	49 (53.8%)	44 (53%)	
Grade III	8 (8.8%)	21 (25.3%)	
Grade IV	2 (2.2%)	8 (9.6%)	
Surgical margins, no. (%)			5 (5.4%)
NSM (R0)	92 (98.9%)	88 (94.6%)	
PSM (R1)	1 (1.1%)		

BMI: Body mass index, EBL: Estimated blood loss, RCC: Renal cell carcinoma, TCC: Transitional cell carcinoma, NSM: Negative surgical margin, PSM: Positive surgical margin. *Statistical Significant p value.

programme supported by continuous technological development and improvement (25). We believe that our study can help beginners in laparoscopy, and the most experienced hands should also know about the standardised complication rates.

Limitations of the study

Our prospective database was created over a long period of over 20 years. During this period, the Clavien classification only changed twice. As such, the probability of bias in recording the complications is inherent. Minor complications (Clavien 1 and 2) could have been easily overlooked at the beginning of laparoscopic surgery when the method was emerging as a safe and viable alternative to open surgery. Another limitation is that we did not evaluate the association between the

patient risk profile [comorbidities status, American Society of Anesthesiologists (ASA) score, tumour characteristics] and postoperative complications. This may be the subject of a future study. A further limitation of this study is that we only reported the standardised complications of rLRN.

The institutional learning curve may have a limited informative value because our data represent results from several surgeons working in a pioneering academic training centre with residents and fellows attending certain procedural steps.

CONCLUSIONS

rLRN is a safe, reproducible technique associated with a relatively low incidence of complications. The learning curve was shorter for the third-generation surgeons; although these surgeons operated on significantly more patients with advanced diseases.

The Clavien-Dindo classification is suitable for assessing rLRN complications and adopting this standardised system can help in the evaluation and comparison of surgical quality of LRN series.

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